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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,116	10/23/2001	Henry Lamparski	348022000501	3354
24353	7590	10/01/2003	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025			VOGEL, NANCY T	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/045,116	LAMPARSKI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nancy Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2001 and 13 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 33,36 and 38-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33,36 and 38-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Claims 33, 36, and 38-50 are pending in the case.

Receipt of amendments on 5/13/02 and 10/23/01 are acknowledged.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 36 and 38-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is vague and indefinite in its recitation of "transcriptional response element (TRE)". It is not clear what is intended by this phrase. Presumably, "transcriptional regulatory element (TRE)" is intended.

Claims 36, 43, 44, 46, 47, 48, 49, and 50 are vague and indefinite in their failure to recite terms such as "nucleotides" or "kilobases" following the recited numbers. Presumably, the numbers recited in claims 36, and 48-50 refer to nucleotides, and the numbers recited in claims 43, 44, 46, and 47 refer to kilobases.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 33, and 38-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Hallenbeck et al. (WO 96/17053).

Hallenbeck et al. teaches a replication competent virus vector in which a gene required for replication is under the control of a tissue-specific regulatory sequence (page 6, lines 14-25). The preferred vector is adenovirus and the gene can be E1A, E1B or any other gene essential for replication, such as E2-E4 (page 17, lines 2-15). The preferred promoter is the carcinoembryonic antigen regulatory sequence (page 10, lines 6-8). The regulatory sequence can be used to control more than one gene (Page 16, lines 12-23). In one embodiment, both E1A and E1B are linked to separate tissue-specific regulatory sequences (page 17, lines 5-6). The reference discloses a composition comprising the adenovirus vector and a pharmaceutically acceptable excipient (page 20, lines 27-30), and host cells transformed with the vector (page 19, lines 15-19).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallenbeck et al. (WO 96/17053) in view of Richards et al. (WO95/14100).

Hallenbeck et al. teaches a replication competent adenovirus vector comprising a gene required for replication is under the control of a tissue-specific regulatory sequence (page 6, lines 14-25). The preferred vector is adenovirus and the gene can be E1A, E1B or any other gene essential for replication, such as E2-E4 (page 17, lines 2-15). The preferred promoter is the carcinoembryonic antigen (CEA) (page 10, lines 6-8). The regulatory sequence can be used to control more than one gene (Page 16, lines 12-23). In one embodiment, both E1A and E1B are linked to separate tissue-specific regulatory sequences (page 17, lines 5-6).

Hallenbeck et al. does not teach a specific CEA-TRE comprising an enhancer from the region of -14.5 to -3.8 relative to the transcriptional start site of the CEA gene or specific sequences. However, Richards et al. teaches a human CEA-TRE which includes sequences identical to SEQ ID NO:1 of the present application and which is used to express heterologous genes in cells which express CEA (page 3). Particular fragments disclosed to be useful are the enhancers located at -14.5 to -10.6, -13.6 to -

10.6 and -6.1 to -3.8 upstream of the transcriptional start site (page 3). All of the regions can be included in either orientation and in different combinations. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the adenovirus vector comprising a CEA-TRE as taught by Hallenbeck et al. and to use the particular sequences of a CEA-TRE disclosed by Richards et al., motivated by the teachings of Richards et al. that the disclosed CEA-TRE sequences are effective for high level expression of a heterologous gene to which they are operably linked.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ntv  
9/26/03

  
TERRY MCKELVEY  
PRIMARY EXAMINER